Docket No.: 101896-31
(PATENT)

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Michael J. O'Neil

Application No.: 09/955,680 | Confirmation No.: 1266

Filed: September 19, 2001 | Art Unit: 3737

For: ALIGNMENT VERIFICATION DEVICE AND METHOD OF USE | Examiner: William C. Jung

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Dated: December 22, 2005 Signature: _____
(Ronald E. Cahill)

MS Appeal Brief - Patents
Commissioner for Patents
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APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

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12/29/2005 SSESHE1 00000041 09955680
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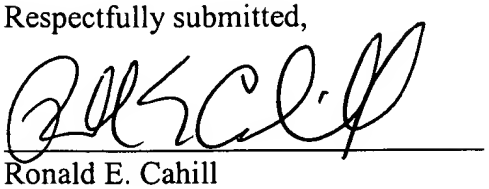
any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 101896-31.

Respectfully submitted,



Dated: December 22, 2005

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I. REAL PARTY IN INTEREST

The real party in interest is DePuy Spine, Inc. of Raynham, Massachusetts. DePuy Spine, Inc. derives its rights in this application by virtue of an assignment of the application by the inventor to DePuy Acromed, Inc., and a subsequent name change from DePuy Acromed, Inc. to DePuy Spine, Inc.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1-21 are currently pending in the present application, Serial Number 09/955,680. According to the Final Office Action mailed on March 22, 2005, each of claims 1-21 stand finally rejected. Accordingly, claims 1-21 are subject to this appeal.

IV. STATUS OF AMENDMENTS

No amendments have been filed subsequent to the final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is directed to a device, system, and method useful for implanting a prosthesis, such as an artificial intervertebral disc, within a patient in a safe and efficient manner. In particular, the invention provides a device, system, and method for aligning an imaging device (an x-ray machine for example) with a spinal disc prosthesis so that a doctor can image the prosthesis (by taking an x-ray image for example) to confirm correct placement of the prosthesis with a single image.

To fully understand the claimed invention, it is first necessary to appreciate the state-of-the art at the time of the Applicant's invention, which represents the background against which the claimed invention was developed.

A. The Problem Addressed by the Invention is the Inefficient Verification of Prosthesis Placement

Following the removal of an diseased or damaged spinal disc, an artificial disc can often be implanted in the resulting space between to two vertebrae so as to maintain the spatial and functional physiological integrity of the spinal column. In order to maintain the natural load bearing and kinematic characteristics of the patient's spine, most spinal implants incorporate either lordotic or kyphotic angles, and a slight rotation of the implant during implantation about the local axis of the spine can cause misalignment of the desired angles significantly affecting the ability to restore lordosis or kyphosis and the desired spinal load transfer and kinematics. (Page 1, lines 28-32.) Thus, in order to prevent misalignment during a disc replacement procedure, an image obtaining device, such as an X-ray machine, is brought into the operating room (typically mounted on a C-arm) in order to image the implanted prosthesis to determine whether it is properly placed within a patient. (Page 1, line 32 – page 2, line 4.)

A key step in obtaining images that can tell the surgeon whether the implant is properly aligned within the patient is to properly align the imaging device itself. (Page 2, lines 6-7.) Many times, this is done in the operating room simply by inserting the prosthetic disc, checking the angular orientation of the disc by visually determining whether an implant inserter tool connected to the disc is extending straight up from the operating table or is relatively aligned with respect to anatomical landmarks, moving the C-arm into position so that the X-ray or other imaging device is directly over the disc, and taking an X-ray or other image. (Page 2, lines 7-13.) If upon viewing the image, the imaging device is not properly aligned for making the needed determination, its position is adjusted and a new image is obtained. (Page 2, lines 13-14.) This process of aligning the imaging device may be required yet again if the implant is not correctly aligned and adjustment of the implant and further implant orientation verification is required, subjecting the patient to multiple x-ray attempts as well as a lengthy procedure. (Page 2, lines 14-17.)

For well known reasons, it is preferable to minimize the patients exposure to x-rays and it would be desirable to take as few x-rays as possible during the procedure. (Page 2, lines 17-19.) In addition, it is also preferable to minimize the amount of time for the overall procedure, and

thus reduce the patients exposure to anesthesia. (Page 2, lines 19-20.) Hence, it is desirable to minimize the time duration involved in the imaging verification step. (Page 2, lines 20-21.)

B. The Invention Solves the Problem by Providing an Alignment Guide for Verifying the Orientation of an Image Taking Device with Respect to the Prosthesis, and a System and Method for Its Use

The claimed invention allows more efficient verification of the placement of an image obtaining device with respect to a surgical implant, especially a spinal disc implant, during the implantation procedure. FIG. 1 of the application, reproduced below, shows an overall system view illustrating the alignment verification device 10 engaged to a prosthesis 102 that has been implanted in the patient's 120 spine. The alignment verification device 10 is being used in the Figure to correctly align an image obtaining device 106, such as an x-ray, with the prosthetic device 102. (Page 5, lines 22-24.) The image obtaining device 106 is generally mounted on a structure 100, such as a C-arm, to allow the image obtaining device 106 to be moved around the operating room and to be oriented as desired. (Page 5, lines 26-28.) In addition, image obtaining device 106 typically includes a sighting element 108, such as a laser pointer, for providing a visual indication as to the aiming or orientation of the image obtaining device. (Page 5, lines 28-31.) This allows the image obtaining device 106 to be correctly oriented before the image is taken, thus insuring that only one image will be necessary to determine whether the prosthesis has been properly implanted.

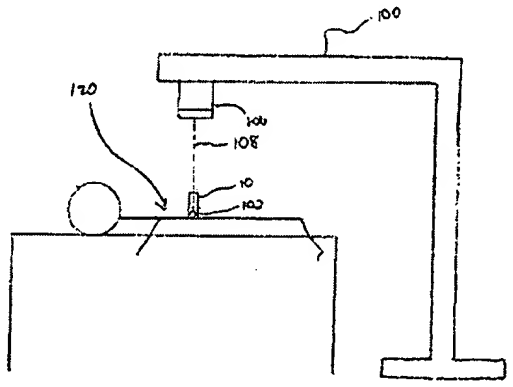


FIG. 1

The alignment verification device 10, shown in Applicant's FIG. 2 (reproduced below) along with a prosthesis 102 to which it is engaged, includes a spacer element 12 having two elongate members 14, 16, and an alignment guide surface 40 defining an alignment orifice 42.

(Page 6, lines 2-4.) The spacer element 12 has an insert engaging element 20 on its distal end which includes individual prosthesis engaging elements 22, 24 on a distal end of each of the elongate members 14, 16, respectively. (Page 6, lines 4-6.) Insert engaging element 20 (via the individual prosthesis engaging elements 22, 24) interacts with prosthesis 102 to place the alignment orifice 42 into a predetermined geometric relationship with, and spaced apart from, the prosthesis 102 so that sighting element 108 can be aimed through alignment orifice 42 to strike a predetermined visual indicator point 26 to provide a visual indication that image obtaining device 106 (shown in FIG. 1) has been placed in a known orientation with respect to prosthesis 102, allowing verification of the orientation of the prosthesis to proceed efficiently, generally with a single image verifying the placement of the prosthesis. (Page 6, lines 6-12.)

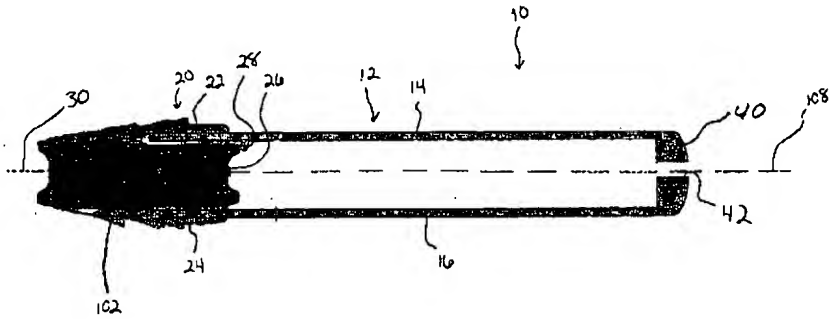


FIG. 2

C. The Three Independent Claims at Issue

The present application has a total of 21 claims, three of which are independent (claims 1, 7, and 19). The independent claims, which were not amended during prosecution, recite as follows:

1. Claim 1 Recites an Alignment Verification Device

Applicant's claim 1 recites an alignment verification device 10. The device 10 includes a spacer element 12 having an insert engaging element 20 disposed on the distal portion thereof. An alignment guide surface 40 is affixed to the spacer element 12 and defines an alignment orifice 42; the alignment orifice 42 is spaced apart from the insert engaging element 20.

2. *Claim 7 Recites a Prosthesis Verification System That Includes the Alignment Verification Device and the Prosthesis*

Applicant's claim 7 recites a prosthesis alignment verification system that includes an alignment verification device 10 and a prosthesis 102. The alignment verification device 10 has a spacer element 12 having a prosthesis engaging element 22, 24 disposed on its distal portion. An alignment guide surface 40 is affixed to the spacer element 12 and defines an alignment orifice 42; the alignment orifice 42 is spaced apart from the prosthesis engaging element 22, 24. The prosthesis 102 has an engaging element 50, 70 and a visual indicator element 26. The engaging element 50, 70 is configured to releasably engage the prosthesis engaging element 22, 24 of the alignment verification device 10 so that, upon engagement, the alignment orifice 42 is spaced apart from the visual indicator element 26.

3. *Claim 19 Recites a Verification Method That Verifies the Orientation of the Image Obtaining Device With Respect to the Prosthesis Using the Alignment Verification Device*

Applicant's claim 19 teaches a method for verifying the orientation of an image obtaining device 106 with respect to an implanted prosthesis 102 that includes providing an alignment verification device 10, and engaging the alignment verification device 10 to the implanted prosthesis 102. The alignment verification device 10 has a spacer element 12 with a prosthesis engaging element 22, 24 disposed on its distal portion. An alignment guide surface 40 is affixed thereto and defines an alignment orifice 42 that is spaced apart from the prosthesis engaging element 22, 24. The prosthesis 102 has an engaging element 50, 70 and a visual indicator element 26, and the engaging element 50, 70 is configured to releasably engage the prosthesis engaging element 22, 24 of the alignment verification device 10 so that, upon engagement, the alignment orifice 42 is spaced apart from the visual indicator element 26. Further, the method includes orienting the imaging obtaining device 106 so that a sighting element 108 on the image obtaining device 106 is aimed through the alignment orifice 42 to the visual indicator element 26 to provide a visual indication that a predetermined orientation between the image obtaining device 106 and the prosthesis 102 has been achieved.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Each of pending claims 1 to 21 stands finally rejected pursuant to 35 U.S.C. § 102(b) as

being anticipated by U.S. Patent No. 4,848,327 to Perdue.

VII. ARGUMENT

A. The Perdue Reference is Directed to a Different Problem Than the Application on Appeal, and Does Not Provide the Claimed Solution

Perdue does not provide an alignment verification device, system or method that enables a surgeon to verify the placement of an implanted prosthesis with a "single shot" from an imaging device (and thereby minimizing the patient's exposure to the imaging rays) by deploying an alignment verification device as claimed. Perdue teaches an alignment guide for placing a screw through a previously implanted intramedullary nail. Perdue uses a fluoroscopic imager – but uses it to guide placement of the screw guide, and begins imaging and "jiggles" the imager until it and the screw guide are properly aligned with the prosthesis. There is no device, system or method for aligning the fluoroscopic imager with the prosthesis before imaging. As a direct result of these differences in purpose, the devices disclosed by Perdue do are not configured as required by the pending claims.

Perdue, in its own words, teaches methods and devices for placing screws in an orthopedic nail 98 used in setting fractures of a long bones 90 of the body. [Abstract.] First, a fluoroscope assembly 106is used to develop an image of the screw hole(s) 100 in the nail 98 on a monitor 112. (Id.) This fluoroscopic image enables the surgeon to adjust the fluoroscope assembly 106 until the x-rays from the fluoroscope 108 are propagated along lines which are coaxially aligned with the screw hole(s) 100 of the nail 98. (Id.)

Once lines from the x-ray correspond to the holes in the nail, a surgeon scribes reference marks, usually in the form of an "X," which correspond to the location of the screw hole(s) 100 on the limb 109 containing the fractured bone 90. [Id.] The surgeon then incises the limb 109 at the reference marks and places tubular drill guide(s) 68 of a jig 8 within the incisions such that the tubular drill guide(s) 68 are set against the bone 90 in a position of coaxial alignment with the screws hole(s) 100 of the nail 98. [Id.] Additionally, so as to fix the location of the jig 8, pin(s) 80 are impaled into the flesh on the opposite side of the limb 109 relative to the drill guide(s) 68. [Column 11, lines 49-62.]

As illustrated in FIG. 5, reproduced below, after the tubular drill guide(s) 68 and the pin(s) 80 are positioned, the fluoroscope assembly 106 again develops an image of the screw hole(s) 100 in the nail 98 on a monitor 112. [Id.; Column 11, line 63 – Column 12, line 2.]

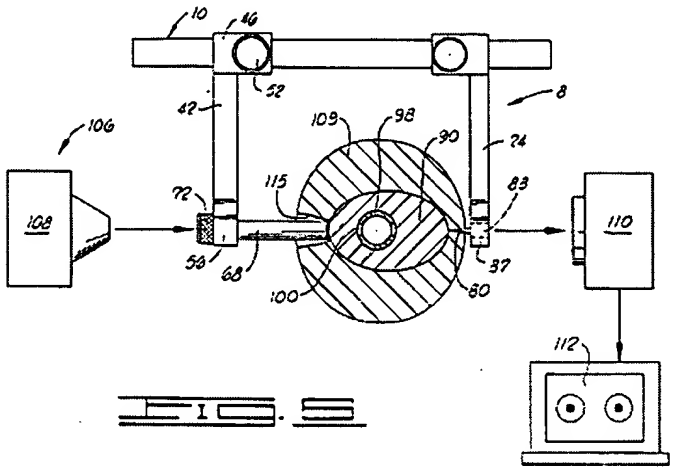


FIG. 5

Following alignment of the drill guide(s) 68, the screw hole(s) 100 and the pin(s) 80 are in coaxial alignment with one another, the screws are inserted through the drill guide(s) 68 and are screwed into the bone 90. (Id.) In particular, as shown in FIG. 6, which is reproduced herein, the jig is set on opposite sides of the fractured bone, and with certain elements of the jig in alignment with the fastener holes through the elongated nail, a drill bit is extended through each of the drill guides 60 and 68, and the cortex or hardened outer portion of the bone 90 is penetrated in each case by the drill bit. At this location, the cortex has been substantially entirely penetrated by the drill, and the relatively soft, spongy bone material, or cancellous, is exposed at the end of the drilled hole.

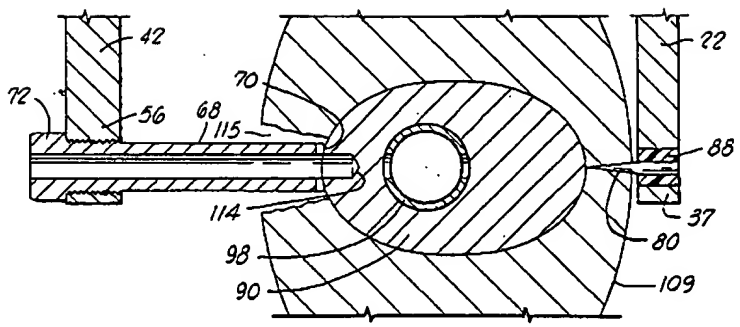


FIG. 6

A screw 120 can then be place through the bone 90 and nail 98 as shown in Figure 8:

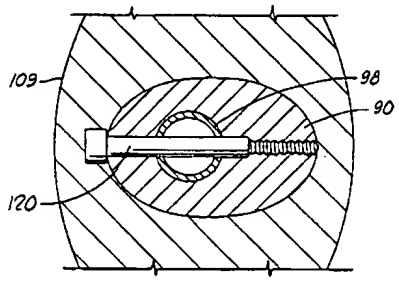


FIG. 8

B. The Examiner Uses Perdue Inconsistently in the Office Actions, Further Indicating that the Devices in Perdue Do Not Disclose the Recited Elements in the Recited Configuration

The Examiner's anticipation rejection in the first office action provided very little detail about which elements of Perdue corresponded to which elements of the claims. In fact, the only element of Perdue that was called out by the Examiner was "elongated spacer element 10" – the rest of the anticipation rejection was nothing more than a recitation of Applicant's claims. That office action provided as follows:

> **Claims 1, 4, 7-11, 16, 17 and 19-21**: Perdue discloses a method and apparatus where an alignment device aligns a verification or guidance device such as x-ray image device. Perdue further discloses that the device described above includes an elongated spacer element 10 having proximal and distal portions and an insert engaging element disposed on the distal portion and an alignment guide surface affixed to the

> spacer element and defining an alignment orifice, the alignment orifice being spaced apart from the insert engaging element. In addition, Perdue discloses that the device described above where the aligning of the x-ray device is used to insert prosthesis during orthopedic surgery. Moreover, the alignment guide surface affixed to the spacer element and defining an alignment orifice, the alignment orifice being spaced apart from the prosthesis engaging element and a prosthesis having an engaging element and a visual indicator element, the engaging element configured to releasably engage the prosthesis engaging element of the alignment verification device so that, upon engagement, the alignment orifice is spaced-apart from the visual indicator element (col. 7, line 46 - col. 8, line 51; col. 9, line 14 - col. 11, line 36).
>
> ***Claims 2, 3, 5, 6, 12-15:*** Perdue's disclosure of alignment device is used in orthopedic procedure. The spinal disc surgery is considered orthopedic procedure, therefore Perdue inherently anticipate the use of the alignment device in spinal disc prosthesis.

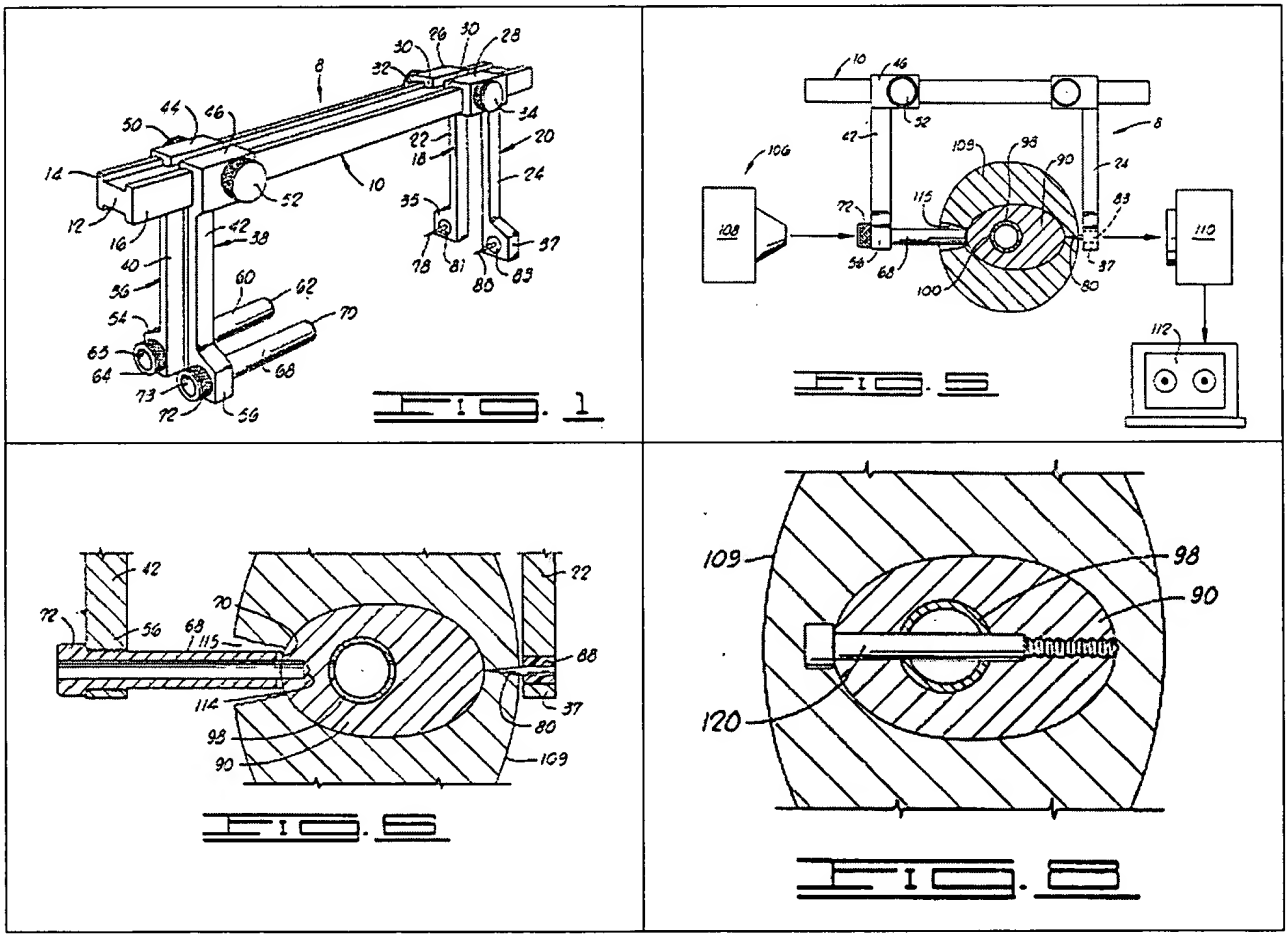
Applicant responded to this office action by providing an overview of his invention, then explaining how it was impossible for Perdue to meet the recitations of the independent claims. The Examiner responded with a Final Rejection that completely changed the basis of the anticipation rejection:

> In regards to applicant's argument on page 2 with reference to figures 1 and 2 on page 3, the examiner has fully considered the description of the applicant's invention, however the disclosure nor the claims over come the prior art cited the previous office action. In Perdue's figure 6, the alignment verification device includes spacer element 68 with two elongated members 72 and alignment guide surface 70 with defining orifice where affixing device such as nail or screw 114 is inserted with engaging element as shown in figure 8. More specifically, the engagement element in figure 8 is threaded screw, i.e., cylinder with slotted element, which is fit to be inserted in spinal disc as prosthesis. Visual indicator as claimed in claims 7 and 19 is disclosed by Perdue in col. 9, lines 14-28. Therefore, Perdue anticipates all claimed features in claims 1, 4, 7, 8, 11, and 17-19.

In an attempt to clarify the rejections so that Applicant can respond to them, Applicant

provides the following chart setting out the rejections of the first and final office actions, along with selected Figures from Perdue that illustrate the elements pointed out by the Examiner:

Claim 1	First Office Action	Final Office Action
1. An alignment verification device, comprising		In Perdue's figure 6, the alignment verification device includes
a spacer element having	elongated spacer element 10 having	spacer element 68
proximal and distal portions and	proximal and distal portions and	with two elongated members 72 and
an insert engaging element disposed on the distal portion; and	an insert engaging element disposed on the distal portion and	the engagement element in figure 8 is threaded screw, i.e., cylinder with slotted element, which is fit to be inserted in spinal disc as prosthesis
an alignment guide surface affixed to the spacer element and defining an alignment orifice, the alignment orifice being spaced apart from the insert engaging element.	an alignment guide surface affixed to the spacer element and defining an alignment orifice, the alignment orifice being spaced apart from the insert engaging element.	alignment guide surface 70 with defining orifice where the affixing device such as nail or screw 114 is inserted with engaging element as shown in figure 8



The inconsistencies in the rejections are immediately apparent. For example, the spacer element of the claim includes a distal insert (or prosthesis) engaging element – the Examiner

does not expressly state where this element is found, but does say that the nail or screw 114 (in fact 114 is a drill bit) "is inserted with engaging element as shown in Figure 8" and that "the engagement element in figure 8 is threaded screw." Figure 8 shows a screw that is a completely different device from the "spacer element" and that never appears to come into contact with the spacer element and so cannot be disposed on a distal portion of the spacer element as recited. The purported spacer element (element 68) never contacts the insert or prosthesis. Claim 1 also recites an alignment guide surface affixed to the spacer element and defining an alignment orifice. The Examiner points to "alignment guide surface 70 with defining orifice" – but surface 70 is located on the distal end of the "spacer element" 68, where the insert engaging element is supposed to be disposed, and the alignment orifice is supposed to be spaced apart from that.

On its face, the outstanding rejection makes little or no sense.

C. Perdue Anticipates No Claims from Among the Claim 1 "Device" Group of Claims

Independent claim 1 is not anticipated by Perdue. Claim 1, the independent device claim, is in many ways the simplest claim in the pending application, and should be the easiest for which to make out an anticipation rejection. However, Perdue, which is directed to a drill guide jig (a very different problem from that addressed by the Applicant), does not anticipate claim 1 because it does not disclose the elements recited in claim 1 in the configuration that they are recited in claim 1. In addition, many of the claims that depend from claim 1 are not anticipated by Perdue for reasons over and above the reasons stated for claim 1.

1. Perdue Fails to Teach or Even Suggest the Recitations of Claim 1 Because Nowhere Does Perdue Teach or Suggest an Alignment Verification Device That Includes an Insert Engaging Element Disposed on the Distal Portion Thereof and an Alignment Guide Surface Affixed to the Spacer Element and Defining an Alignment Orifice, the Alignment Orifice being Spaced Apart from the Insert Engaging Element

Applicant's claim 1 recites an alignment verification device including an insert (or prosthesis) engaging element disposed on a distal portion of its spacer element, and an alignment guide surface affixed to the spacer element and defining an alignment orifice, the alignment orifice being spaced apart from the insert engaging element.

a. Purdue does not disclose or suggest the Alignment Verification Device of Claim 1 because it does not disclose an spacer element having an insert engaging element on a distal portion thereof

Perdue does not teach or even suggest the recitations of claim 1, and in particular, Perdue does not teach an alignment verification device which includes an insert engaging element disposed on the distal portion. Referring to the Examiner's original basis for anticipation (the spacer element as disclosed by Perdue's "elongated channel element 10"), as can be seen from FIG. 5 of Perdue above, the distal portion of Perdue's element 10 includes a pin which is stuck in the flesh of the patient opposed to the drill guide(s). Given that the pin neither contacts the screw or the nail, in no way does this pin act as an insert engaging element, but rather helps to stabilize the jig.

Referring to the more recent rejection in which the "elongated tubular drill guide 68" of Perdue is said to correspond to the spacer element – guide 68 likewise does not have a distal insert (or prosthesis) engaging element. It contacts the patient's bone on its distal end. To the extent that the Examiner suggests that the distal insert engaging element is provided on the drill bit 114 or the screw 120 of Purdue, the drill bit does not contact the prosthesis, and the screw does not engage the prosthesis on its distal end (nor does act as the spacer as it is not affixed to the guide element).

b. Purdue does not disclose or suggest the Alignment Verification Device of Claim 1 because it does not teach an alignment orifice spaced apart from the insert engaging element on the distal portion

Perdue also does not teach an alignment guide surface affixed to the spacer element and defining an alignment orifice, the alignment orifice spaced apart from the insert engaging element (which is on the distal portion of the spacer). The only argument provided by the Examiner is that the "serrated end face 70" is an alignment guide surface defining an orifice. Even if the serrated end face is seen as a surface defining an orifice, it is not spaced apart from an insert engaging element (Perdue doesn't disclose an insert engaging element) as the orifice extends to the very distal end of the structure and would be the same.

In addition, any "orifice" provided on the drill guide 68 is not an "alignment guide surface . . . defining an orifice" because, as described in the portions of Perdue related above, the fluoroscope is aligned first – and only then is the drill guide put into place. The drill guide is not intended to be and does not act as an alignment guide surface in any way.

2. *Perdue Fails to Teach or Even Suggest the Additional Recitations of Claims 2 and 3 That the Insert Engaging Element is Rectangular and That it Further Includes a Depth Stop Element*

Claims 2 and 3 fall within a subset of the claims for which the Examiner admits that Perdue provides no teaching – but for which the Examiner relies on inherency to make rejections as anticipated. The Examiner is wrong on both the facts and the law.

Applicant's claim 2 recites an insert engaging element that is generally rectangular and is sized to fit within a slot formed on the surface of a spinal disc insert prosthesis. This feature is significant in that it allows the alignment verification device to engage the spinal disc insert prosthesis in the same way that the insertion tool for the prosthesis does. In this way, no extra features on the prosthesis are required to perform the alignment verification of the invention. The Examiner does not point to, and Applicant does not find, any disclosure in Perdue that either expressly or inherently teaches a rectangular insert engaging element or prosthesis engaging element. The drill guide 70 of Perdue is cylindrical, and the pin 80 is sharp – not rectangular. Accordingly, Applicant's claim 2 is not anticipated by Perdue. Perdue does not "necessarily" disclose rectangular shapes – rather it simply Further, Perdue says nothing about spinal disc prostheses.

Applicant's claim 3 depends from claim 2 and recites that the insert engaging element includes a depth stop element. In the final office action, the Examiner points to FIG. 8 of Perdue and argues that, "Perdue's figure 8 shows that engaging element has finite length defined by the void created by the drilling tool and the depth of the engaging element is limited to the depths." However, the Examiner does not point to, and Applicant does not find, any disclosure in Perdue that either expressly or inherently teaches a depth stop element. Contrary to the assertion of the Examiner, FIG. 8 illustrates a screw having been placed through the orthopedic nail, and transversely of the bone – it does not illustrate a "spacer element" at all, so it cannot show a

spacer element having a depth stop element. Nowhere does FIG. 8 illustrate any type of depth stop element. Accordingly, Applicant's claim 3 is not anticipated by Perdue.

3. Perdue Fails to Teach or Even Suggest the Additional Recitations of Claim 4 That the Spacer Element Includes Two Elongate Members with the Alignment Guide Fixed Between Them

Applicant's claim 4 recites a device wherein the spacer element includes two elongate members with the alignment guide fixed between the elongate members, each elongate member having an insert engaging element. Here, the Examiner's argued anticipation of claim 1 completely breaks down. The Examiner argues that the alignment guide defining an alignment orifice is disclosed by element 70 in Perdue – a serrated edge on the distal end of a drill guide tube. Even if the two drill guide tubes could be argued to be the two elongate members of the spacer element – there is no alignment surface defining an alignment orifice ***fixed between them***. The Examiner's own argument puts the alignment orifice someplace else – namely, at the distal end of each drill guide tube.

The Examiner does not point to, and Applicant does not find, any disclosure in Perdue that either expressly or inherently teaches a spacer element which includes two elongate members with the alignment guide fixed between the elongate members, each elongate member having an insert engaging element. Accordingly, Applicant's claim 4 is not anticipated by Perdue.

4. Perdue Fails to Teach or Even Suggest the Additional Recitations of Claims 5 and 6 That the Insert Engaging Element is Rectangular and That it Further Includes a Depth Stop Element

Claims 5 and 6 depend from claim 4, and make substantially similar recitations to claims 2 and 3. Accordingly, claims 5 and 6 are further patentable over Perdue above and beyond claim 4 for the same reasons as explained for claims 2 and 3 above.

D. Perdue Anticipates No Claims from Among the Claim 7 "System" Group of Claims

Independent claim 7 is not anticipated by Perdue. Claim 7, the independent "system" claim, recites an alignment verification device substantially similar to that of claim 1, in combination with a prosthesis with certain relationships between the alignment verification

device and the prosthesis further recited. Perdue does not anticipate claim 7 because it does not teach or suggest the alignment verification device (for the same reasons as recounted for claim 1 above), does not teach or suggest an alignment verification guide that has a releasably engageable relationship with the prosthesis, and does not teach or suggest a visual indicator on the prosthesis that is spaced apart from an alignment orifice on the alignment verification guide. In addition, a number of the claims depending from claim 7 recite further features (including the prosthesis being a spinal disc prosthesis) that are not taught or suggested by Perdue.

1. Perdue Fails to Teach or Even Suggest the Recitations of Claim 7 Because Nowhere Does Perdue Teach or Suggest the Recited Alignment Verification Device, Its Releasable Engagement with the Prosthesis, or Its Relationship to a Visual Indicator on the Prosthesis

Applicant's claim 7 is an independent claim that recites a prosthesis alignment verification ***system*** comprising an alignment verification ***device*** and a ***prosthesis***. Like claim 1, the alignment verification device includes a spacer element having a prosthesis engaging element disposed on the distal portion. Further like claim 1, an alignment guide surface is affixed to the spacer element where it defines an alignment orifice that is spaced apart from the prosthesis engaging element. The prosthesis has an engaging element and a visual indicator element where the engaging element is configured to releasably engage the prosthesis engaging element of the alignment verification device.

There are at least three reasons why Perdue does not anticipate (or render obvious) claim 7.

a. Purdue does not disclose or suggest the Alignment Verification Device of Claim 7 for the same reasons that it does not for Claim 1

Claim 7 is a system claim that recites an alignment verification device, a prosthesis, and a relationship between the alignment verification device and the prosthesis. The alignment verification device recited in claim 7 is substantially the same as the alignment verification device of claim 1 – Perdue does not disclose or suggest the alignment verification device of claim 7 for all of the same reasons that Perdue does not disclose or suggest the elements of claim 1 recounted above. Perdue neither teaches an alignment verification device which includes an

insert engaging element disposed on the distal portion, nor an alignment orifice (let alone one spaced apart from the insert engaging element).

b. Purdue does not disclose or suggest an Alignment Verification Device That is Releasably Engageable With the Prosthesis

The alignment verification device recited as part of the system of claim 7 includes a prosthesis engaging element on a distal portion of its spacer element. The prosthesis recited as part of the system of claim 7 further includes an engaging element. Importantly, the engaging element is configured to releasably engage the prosthesis engaging element of the alignment verification device so that the alignment orifice is spaced apart from a visual indicator element on the prosthesis. Perdue discloses no such combination.

Referring, for example, to Figures 5, 6 and 8 of Perdue, there are no prosthesis engaging elements on any alignment verification device. There are no engagement features on any prosthesis. No alignment verification device is ever engaged to a prosthesis – and certainly no alignment verification device is engaged to a prosthesis so as to space an alignment orifice on the alignment verification device apart from a visual indicator element on the prosthesis.

The Examiner's stretch to try to make an "engagement element" out of the implanted screw (screw 120, Figure 8 of Perdue) illustrates an important principal about the failures of Perdue as a reference against this and other claims. Perdue does not provide a structure for aligning an imaging device so that the placement of a prosthesis can be verified in just "one shot." Perdue starts imaging and "wiggles" his imaging device to get it aligned before placing any of the instruments. The instruments are then used to guide a drill. Because the context of Perdue is so very different from the problem addressed by the Applicant, the structures used have very different configurations. The various pieces and parts of the Perdue drill guide pointed to by the Examiner simply do not come together in the manner recited in the present claims. The screw cannot have the recited prosthesis engaging element because it is not a distal portion of a spacer element that is affixed to the alignment guide surface as recited – as a result, it cannot space the alignment orifice apart from a visual indicator on the prosthesis as is further recited in the claim.

c. Purdue does not disclose or suggest the Prosthesis Alignment Verification System Having Visual Indicator Element on the Prosthesis that is Spaced Apart from the Alignment Orifice

Perdue also does not teach a prosthesis having a visual indicator element, which, when the prosthesis and alignment verification device are engaged, is spaced apart from the alignment orifice. The Examiner responds: "Visual indicator as claimed in claims 7 and 19 is disclosed by Perdue in col. 9, lines 14-28." This portion of Perdue, reproduced below along with Figure 1, which illustrated the described elements, speaks to the pins 78, 80 on the jig 8 – not to a visual indicator ***on the prosthesis*** as recited. According to Perdue's own words, these pins do not even contact the prosthesis, they stick the patient to stabilize the jig. The pins cannot be visual indicators on the prosthesis, and there is no other disclosure in Perdue to make up for this failing.

Column 9, lines 14 to 28 of Perdue:

The method of mounting the pins 78 and 80 in the foot portions 38 and 37 is important to carrying out the method of the present invention. Thus, each pin 78 and 80, although itself x-ray opaque, is mounted securely and fixedly in the center of a small disc or cylinder of x-ray transparent synthetic resin material 81 or 83. This arrangement results in a visually contrasting pattern on an x-ray display panel, which contrasting pattern resembles a bulls-eye target, with the material in the disc or cylinder which is x-ray transparent causing the outer portion of the target to be relatively lighter, and the pins 78 and 80 causing the development of the bulls-eye central dot. This explanation will be more thoroughly understood from the ensuing description when reference is made to FIGS. 3, 3a and 4 of the drawings.

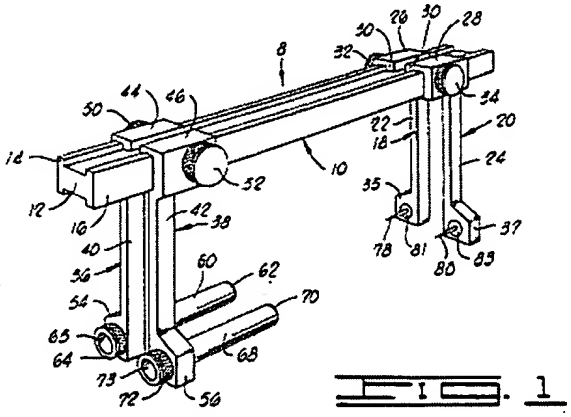


FIG. 1

*2. **Perdue Fails to Teach or Even Suggest the Additional Recitations of Claim 8 That the System is Adapted to Permit a Sighting Element to be Aligned with the Alignment Orifice and the Visual Indicator Element***

Applicant's claim 8, which depends from claim 7, recites a prosthesis alignment verification system wherein the engagement of the alignment verification device with the prosthesis is adapted to permit a sighting element of an image obtaining device to be aligned with the alignment orifice and the visual indicator element. In the pending application, one such sighting element is disclosed as a laser pointing element. The Examiner does not point to, and Applicant does not find, any disclosure in Perdue that either expressly or inherently teaches a

system wherein engagement of the alignment verification device with the prosthesis is adapted to permit a sighting element of an image obtaining device to be aligned with the alignment orifice and the visual indicator element. According to the Examiner, the visual indicator element is taught by the pins on the distal end of Perdue's jig. But these pins never have a line of sight back to the image obtaining device, and so Perdue can have no adaptation to permit such a sighting element. If a person of ordinary skill were to add a sighting element to the image obtaining device of Perdue for some reason, it would point only to the patient as there is never a time where an orifice is placed in a line of sight with Perdue's prosthesis (the orthopedic nail). Accordingly, Applicant's claim 8 is not anticipated by Perdue for this additional reason.

3. *Perdue Fails to Teach or Even Suggest the Additional Recitations of Claims 9 and 10 That the Insert Engaging Element is Rectangular and That it Further Includes a Depth Stop Element*

Claims 9 and 10 depend from claim 8, and make substantially similar recitations to claims 2 and 3 that the insert engaging element is rectangular and that it further includes a depth stop element, respectively. Accordingly, claims 9 and 10 are further patentable over Perdue above and beyond claim 8 for the same reasons as explained for claims 2 and 3 above.

4. *Perdue Fails to Teach or Even Suggest the Additional Recitations of Claim 11 That the Spacer Element Includes Two Elongate Members, Each Having a Prosthesis Engaging Element*

Applicant's claim 11 depends from claim 9 and recites a prosthesis alignment verification system wherein the spacer element includes two elongate members with each elongate member having a prosthesis engaging element. The prosthesis is further described as including two engaging elements, each configured to engage one of the prosthesis engaging elements.

In the Final Office Action, the Examiner refers to Perdue's Figure 6 as disclosing an alignment verification device having a "spacer element 68 with two elongated members 72 . . ." Element 68 is a drill guide tube and element 72 is a knurled finger knob. It is clear from the figures that the knurled finger knob 72 (which is on the proximal end of "spacer element" or drill guide 68) does not have a prosthesis engaging element on its distal end – not only does Perdue not disclose two elongate members with prosthesis engaging elements on their distal ends, Perdue does not disclose one of them.

Still further, the Examiner does not point to, and Application cannot find, any disclosure in Perdue that describes a prosthesis having two engaging elements, with each one being engageable with one of the prosthesis engaging elements found on the distal portion of the respective elongate members.

These features are clearly illustrated in Applicant's specification, showing individual prosthesis engaging elements 22, 24 on a distal end of each of the elongate members 14, 16, respectively, engaging individual elements on the prosthesis:

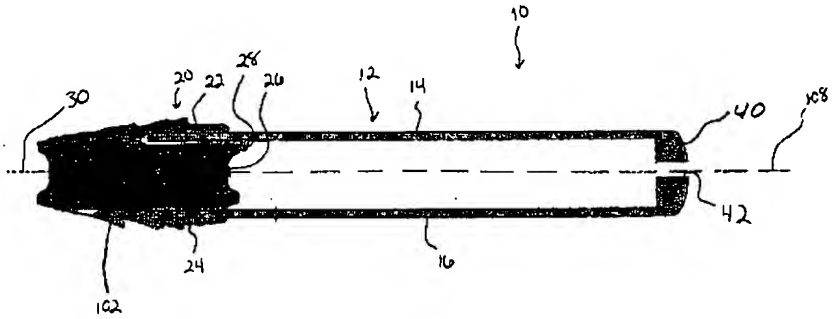


FIG. 2

Perdue never discloses these features as its device never contacts the prosthesis 98, much less engage it twice on the distal portions of each of two elongate members:

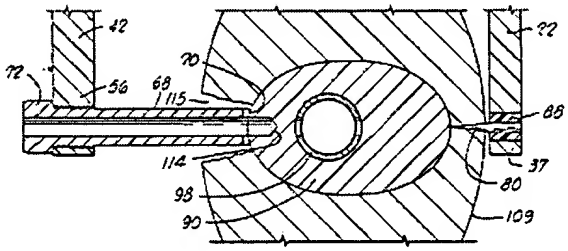


FIG. 6

5. *Perdue Fails to Teach or Even Suggest the Additional Recitations of Claims 12 and 13 as Purdue Never Teaches or Suggests a Spinal Disc Prosthesis, Nor is One Inherent in Perdue*

Applicant's claim 12 recites that the prosthesis is a spinal disc prosthesis, and Applicant's claim 13 recites that the spinal disc prosthesis incorporates an angle. Applicant and the

Examiner are in complete agreement that the Perdue reference does not disclose, teach or suggest anything about spinal disc prostheses.

In the Final Office Action, the Examiner, argues that:

> in regard to inherency, the application of Perdue's invention deals with orthopedic procedure, which includes spinal cord. Although, Perdue do not explicitly state that his device is used for spinal surgery, it is part or a subset of orthopedic surgery.

It should be noted that Perdue never suggests that its invention includes the spinal cord, that is the Examiner's view of the field of orthopedics.

Further, the Examiner reiterates his position from the first Office Action, that:

> **Claims 2, 3, 5, 6, 12-15:** Perdue's disclosure of alignment device is used in orthopedic procedure. The spinal disc surgery is considered orthopedic procedure, therefore Perdue inherently anticipate the use of the alignment device in spinal disc prosthesis.

Perdue does not inherently anticipate Applicant's claims as it does not "necessarily" disclose a spinal disc prosthesis – rather it discloses an intramedullary nail, a completely different thing.

What Perdue actually discloses is an improved system and method for fixing an orthopedic locking nail in the medulla of a patient's long bone. Perdue does not apply its teachings to all of orthopedics, but to stabilizing fractures in a long bone – essentially, one species of orthopedic procedure. Just because the specific application of the present invention could be classified as being within the same general field as Perdue's specific application, there is no basis for the position that Perdue necessarily discloses the Applicant's invention – and even if Perdue did disclose the use of its drill guide jig for use in orthopedic procedures generally, that still is not a disclosure, inherently or otherwise, of providing an alignment verification device with a spinal disc prosthesis. Perdue does not inherently disclose a spinal disc prosthesis, it discloses something completely different – an intramedullary nail.

MPEP § 2112 states:

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic . . . ***To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference,*** and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient... (internal citations and parentheticals omitted; emphasis added).

Still further, MPEP § 2112 continues:

> [I]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." (internal citations and parentheticals omitted; emphasis in original).

Here, there is no basis whatsoever in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics recited in Applicant's claims (a spinal disc prosthesis) necessarily flow from the teachings of Perdue (an intramedullary nail).

6. Perdue Fails to Teach or Even Suggest the Additional Recitations of Claim 14 That the Spinal Disc Prosthesis Includes a Slot as the Engaging Element

Applicant's claim 14 depends from claim 12 (which recites that the prosthesis is a spinal disc prosthesis) and recites that the spinal disc prosthesis includes at least one bone facing surface having a slot as the engaging element and the prosthesis engaging element is sized to engage the slot. Perdue's prosthesis (the intramedullary nail 98) does not have a bone facing surface that has a slot in it for receiving the prosthesis engaging element on the distal portion of the spacer element.

The Examiner appears to find, in the final Office Action, a disclosure in Perdue as:

> the engagement element in figure 8 is threaded screw, i.e., cylinder with slotted element, which is fit to be inserted in spinal disc as prosthesis.

Figure 8 of Perdue is a cross-section of a patient's leg 109, with an intramedullary nail 98 extending into the page within a long bone 90 (such as the femur or tibia) with an orthopedic screw 120 extending transversely through the nail 98.

There is nothing in Figure 8, or in the Examiner's description of Figure 8, or anywhere else in Perdue that discloses the recitations of claim 14. Accordingly, Applicant's claim 14 is not anticipated by Perdue.

7. *Perdue Fails to Teach or Even Suggest the Additional Recitations of Claim 15 That the Spacer Element Includes Two Elongate Member, Each Having a Prosthesis Engaging Element Sized to Engage Two Slots on the Spinal Disc Prosthesis*

Applicant's claim 15 has a chain of dependencies that extends through claim 7 (reciting a system having an alignment verification device and a prosthesis), claim 8 (reciting the sighting of a visual indicator on the prosthesis through the alignment verification device), claim 12 (reciting that the prosthesis is a spinal disc prosthesis), and claim 14 (reciting that the spinal disc prosthesis has a bone facing surface having a slot for engagement by the prosthesis engaging element of the spacer). Claim 15 further recites that the spacer element includes two elongate members each having a prosthesis engaging element sized to engage each of two slots on the spinal disc prosthesis. The Examiner's only reference to claim 15 in the Office Actions is:

> **Claims 2, 3, 5, 6, 12-15:** Perdue's disclosure of alignment device is used in orthopedic procedure. The spinal disc surgery is considered orthopedic procedure, therefore Perdue inherently anticipate the use of the alignment device in spinal disc prosthesis.

The prosthesis disclosed in Perdue is an intramedullary nail 98 located within a bone 90 as illustrated in , Applicant cannot find, expressly or inherently, two bone facing surfaces on the prosthesis with each having a slot formed therein. Applicant further cannot find an alignment device having two elongate members with each member having a prosthesis engaging element on a distal portion thereof to engage the slots. Claim 15 is not anticipated by Perdue.

8. *Perdue Fails to Teach or Even Suggest the Additional Recitations of Claim 16 That the System Includes an Inserter Tool That Has a Prosthesis Engaging Element that Conforms to the Prosthesis Engaging Element of the Alignment Verification Device*

The system of claim 16 (which depends from claim 7) includes a prosthesis, a prosthesis inserter tool, and an alignment verification device. The inserter tool and the alignment verification device each have a prosthesis engaging element that conform substantially in shape to the other so that prosthesis inserter tool and the alignment verification device can each engage the same engaging element on the prosthesis. In the final Office Action, the Examiner addresses claim 16 as follows:

> In regard to claims 16 and 20, claims merely recites that the spacer element can accommodate the prosthesis engaging tool, which is illustrates in figures 6 and 8 where the nail drilled into a patient through the spacer and the same spacer element used to place engaging element 120.

First, the Examiner mischaracterizes the claim. The claim requires the prosthesis inserter tool and the alignment verification device to have substantially the same prosthesis engaging elements. In the Applicant's invention, this allows a surgeon to deploy the prosthesis inserter tool to insert the prosthesis into place. The surgeon can then remove the inserter tool, and engage the alignment verification device to the same feature or features on the prosthesis that the inserter used. In this way, the prosthesis does not have to be made with separate features to engage the two different tools, and the feature or features to which the inserter is attached are sure to be accessable to the surgeon upon removal of the inserter tool. The Examiner mischaracterizes this as "the spacer element can accommodate the prosthesis engaging tool" – that is not what the claim says. The claim actually says that there is an engaging element on the prosthesis that can accommodate both the prosthesis engaging element on the inserter tool and the prosthesis engaging element on the alignment verification device.

Second, the Examiner gets the facts of Perdue wrong. The Examiner says that "the nail drilled into the patient through the spacer and the same spacer element used to place engaging element 120." It is impossible for the "spacer element" (drill guide 68), as illustrated in Figures 6 and 8 (reproduced again below), to be used to place the screw 120 because the head of the

screw won't fit in the guide. The drill guide 68 is used to guide drill 114 which creates a hole that corresponds to the diameter of the shank of the screw 120. The head of screw 120 is necessarily wider than the hole in the bone for the shank, and it will not fit in the drill guide. Perdue does not disclose working in the way that the Examiner suggests in the rejection, and, in fact, it is impossible for Perdue to work the way that the Examiner describes.

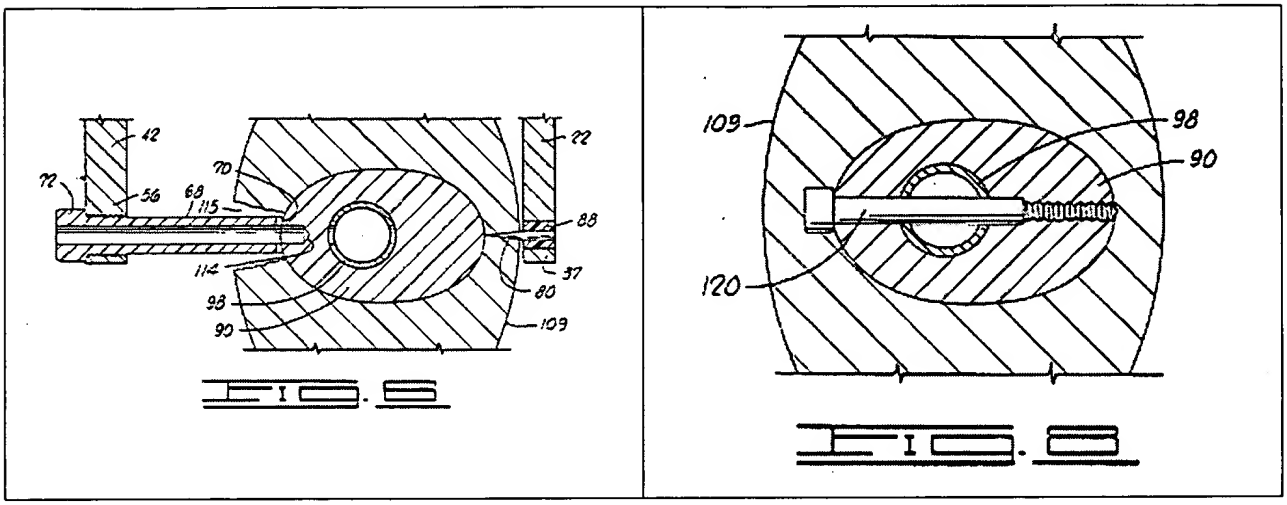


FIG. 8

FIG. 8

Third, setting aside the Examiner's incorrect characterization of claim 16 and the Examiners impossible characterization of Perdue's disclosure, Perdue cannot anticipate because it discloses no prosthesis that is engaged both by a prosthesis inserter tool and by an alignment verification device. Perdue discloses two implanted devices: the intramedullary nail 98 and the screw 120. The intramedullary nail is engaged by the screw 120, and possibly by the drill 114 – neither one is an inserter tool, and neither one is an alignment guide having the recited features. The screw 120 is not engaged by any tool disclosed in Perdue as it is inserted after the drill and the drill guide are removed. It is impossible for Perdue to anticipate claim 16.

9. Perdue Fails to Teach or Even Suggest the Additional Recitations of Claims 17 and 18 That the System Includes an Image Obtaining Device Having a Sighting Element Aimable Through the Alignment Orifice to the Visual Indicator on the Prosthesis

Applicant's claim 17 recites a system having a prosthesis, an alignment verification device, and an image obtaining device having a sighting element that aids in orienting the image obtaining device. The sighting device is aimable through the alignment orifice to the visual

indicator element to provide a visual indication that the image obtaining device is oriented in a predetermined orientation with respect to the prosthesis. In this way, the image orientation of the image obtaining device can be assured, and a verification image can be taken in a "single shot." Claim 18 further recites that the sighting element is a laser pointer. In this preferred embodiment, an imager (such as an X-ray imager 106) can be reoriented until the laser pointer 108 is aimed through the alignment orifice 42 on the alignment verification device 10 to strike the visual indicator 26 on the prosthesis 20 that is spaced apart from the orifice as illustrated in Figures 1 and 2 of the application:

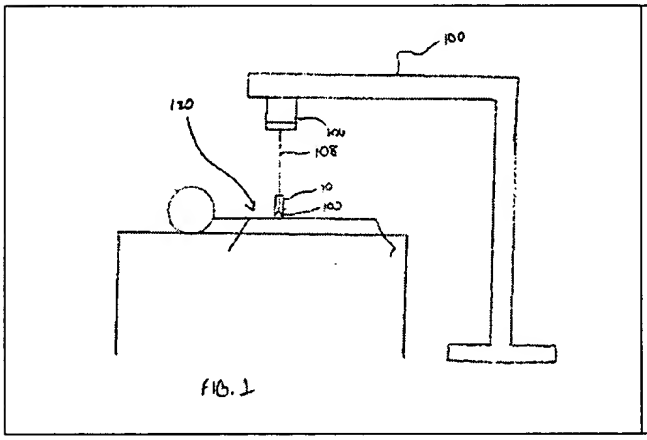


FIG. 1

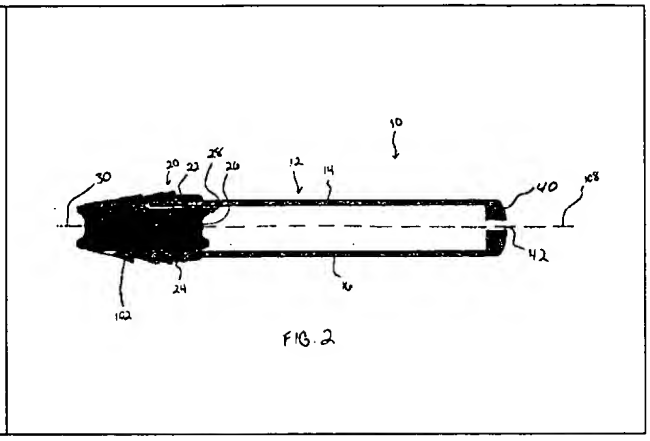


FIG. 2

Perdue clearly discloses an imaging obtaining device. In fact, Perdue uses a fluoroscopic imager – but turns it on and uses it to guide placement of the alignment guide rather than using an alignment verification device and a sighting element to align the fluoroscopic imager before imaging. Perdue discloses no sighting element. Instead, Perdue turns on the fluoroscopic imager and "jiggles" it until it the images taken by it show that it is properly aligned. This process is described by Perdue in Column 10:

The fluoroscope assembly 106 is used in this first step of the invention to align the head 108 so that it directs the x-ray beam precisely along lines of propagation which are coincident with the axes of the screw holes 100 and 102 through the orthopedic nail. Any skewing or angling of the direction of propagation of the x-rays can be discerned by reference to the image portrayed on the readout device or monitor 112. At a time when the x-rays are passing directly through the screw holes 100 and 102 along lines which are in colinear alignment with the axes of these screw holes, perfectly round images will be displayed on the monitor 112 and such are shown at A in FIG. 3.

If the head 108 is angled slightly with respect to the axes of the holes 100 and 102, so that the x-ray beam is not precisely aligned with the axes of these screw holes, then the appearance of the screw hole images A on the monitor 112 will be an elliptical or oval shape, as shown in FIG. 3A, rather than the perfectly circular shape in correspondence to the precise circular cross-sectional configuration of the screw holes 100 and 102. Slight adjustments are made in the positioning of the fluoroscopic head 108 until such time as the image portrayed on the monitor 112 indicates that the x-rays are being transmitted along lines which are in precise alignment with the axes through the round cross-sectioned screw holes 100 and 102.

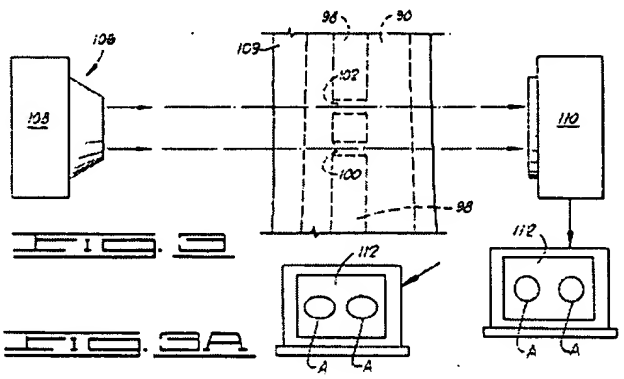


FIG. 3

FIG. 3A

Turning now to the rejection, the Examiner never explains how it is that Perdue is purported to anticipate claim 17, but the Examiner does have this to say about claim 18:

> Claim 18: Perdue also discloses optical visual marker, although not explicitly stated as laser marker, to create sight line for the insertion element, which may include laser pointer (col. 11, lines 19-36).

Resort to the cited portion of Perdue is enlightening. Again, instead of using a sighting element (Perdue does not provide one), Perdue leaves the fluoroscopic imager on and continues to expose the patient to radiation while health-care personnel mark the patient's skin with a crayon:

The person using the marking device 113 is aided in making these markings by the fact that the point will be somewhat opaque to the x-rays, and thus can be guided into the center of the imaged circular area which represents an x-ray transparent zone equivalent to the open cross-sectional area of each screw hole. The appearances of the images which appear upon the monitor 112 following such marking is shown in FIG. 4 where the black dots, D, in the centers of the bulls-eyes represent the marks which have been made on the skin of the limb 109.

This marking procedure is then repeated by making two marks on the opposite side of the limb 109 containing the fractured bone. These marks are also disposed in the lines of the x-ray beam through the screw holes 100 and 102, as evidenced by the fact that these markings, too, are guided into and centered within the two circular areas corresponding to the x-ray transparent cross-sectional area of the two screw holes.

After the markings or indicia have been placed on the skin, using the described technique in which the x-rays from the fluoroscope assembly are used for precise mark alignment, the fluoroscopic head 108 is locked in position, as are the other components of the fluoroscope, so that the x-rays will again be transmitted along lines which are in precise alignment with the axes of the screw holes 100 and 102 in the nail 98 at a time when the fluoroscope assembly is re-energized later in the process of the invention.

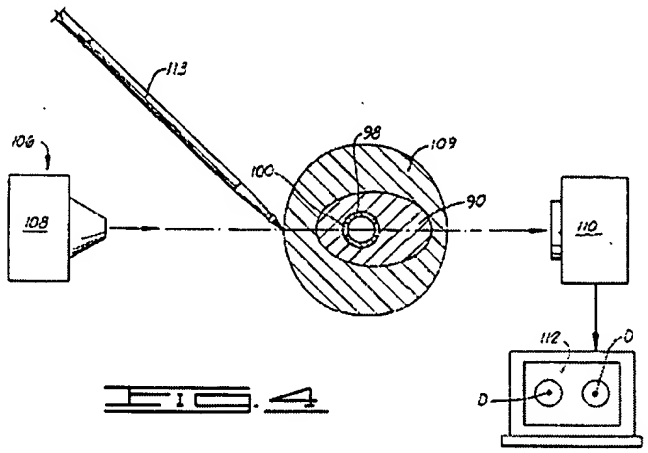


FIG. 4

Nowhere in this or any other portion of the patent does Perdue disclose either the alignment verification device or the sighting element, much less the recited relationship where the alignment verification device includes an alignment orifice that is spaced apart from a visual indicator on the prosthesis and the sighting element is aimed through the orifice to strike the visual indicator to indicate that the imaging device is properly aligned. Claims 17 and 18 are not anticipated by Perdue.

E. Perdue Anticipates No Claims from Among the Claim 19 "Method" Group of Claims

Independent claim 19 is not anticipated by Perdue. Claim 19, the independent "method" claim, recites the provision of an alignment verification device substantially similar to that of claim 1; engaging the alignment verification device to an implanted prosthesis; and orienting an image obtaining device so that a sighting element on the image obtaining device is aimed through the alignment orifice (provided on the alignment verification device) to a visual indicator element (on the prosthesis, spaced apart from the alignment orifice) to provide a visual indication that a predetermined orientation has been achieved.

1. Perdue Fails to Teach or Even Suggest Any of the Recitations of Claim 19

Applicant's claim 19 is an independent method claim that recites providing an alignment verification device, engaging the alignment verification device to a prosthesis so that an alignment orifice on the alignment verification device is spaced apart from a visual indicator on a prosthesis, and orienting an image obtaining device so that a sighting element is aimed through the alignment orifice to the visual indicator element on the prosthesis in order to provide a visual indication that the image obtaining device has been properly oriented. None of these three steps is anticipated by Perdue.

a. Purdue does not disclose or suggest providing the Alignment Verification Device of Claim 19 for the same reasons that it does not for Claims 1 and 7

Claim 19 recites providing an alignment verification device having the same elements as recited in the device of claim 1 and in the alignment verification device that is part of the system of claim 7. The step of providing the alignment verification device in claim 19 is not anticipated by Perdue for all of the reasons that claim 1 is not anticipated and that the alignment verification device recitation of claim 7 is not anticipated.

b. Purdue does not disclose or suggest engaging the Alignment Verification Device to the Prosthesis so that the alignment orifice is spaced apart from the visual indicator element

Claim 19 further recites engaging the alignment verification device to the implanted prosthesis so that the alignment orifice is spaced apart from the visual indicator on the prosthesis. As explained above with respect to claim 7 (which recites a system having the alignment device releasably engageable with the prosthesis to achieve the spacing), Perdue does not disclose any device that engages the prosthesis to space an alignment orifice apart from a visual indicator on the prosthesis.

c. Purdue does not disclose or suggest orienting an image obtaining device so that a sighting element is aimed through the alignment orifice to the visual indicator element to indicate that a predetermined orientation has been achieved

Claim 19 recites orienting the image obtaining device so that a sighting element on the

device achieves a certain position, indicating that a predetermined orientation for the device with respect to the prosthesis has been met. As noted extensively above, Perdue orients his image obtaining device, a fluoroscope, by turning it on and continually reorienting it until the desired image appears – Perdue does not use a sighting device to align his image obtaining device with respect to his prosthesis. This argument is recounted in further detail with respect to claim 17 above.

2. *Perdue Fails to Teach or Even Suggest the Recitations of Claims 20 and 21 of Engaging and Disengaging of an Insertion Tool that Engages with the Same Element on the Prosthesis that the Alignment Verification Device Engages To*

Applicant's claim 20 depends from claim 19 and recites a method for verifying the orientation of an image obtaining device with respect to an implanted prosthesis where, before the alignment verification device is deployed to orient the image obtaining device, an insertion tool is engaged to, then disengaged from, the prosthesis using the same engaging element or elements on the prosthesis that the alignment verification device engages to. First, Perdue "jiggles" his fluoroscope to align it before his jig is deployed, so Perdue cannot meet the timing of the steps recited in claim 20. Further, for the same reasons as recounted above for claim 16, Perdue does not disclose an inserter and an alignment verification device that are engageable to the same element or elements on the prosthesis. Accordingly, claims 20 and 21 cannot be anticipated by Perdue.

The Examiner has further provided a specific explanation of the rejection of claim 21 as follows:

> In regard to claim 21, Perdue's figure 8 also shows that the engaging element 120 which is previously engaged with the insertion tool is disengaged from the tool.

However, the Examiner does not point to, and Applicant does not find, any disclosure in Perdue that either expressly or inherently teaches an inserter tool having a prosthesis engaging element conforming substantially in shape to the prosthesis engaging element of the alignment verification device so that each prosthesis engaging element can engage the same engaging element on the prosthesis.

VIII. CONCLUSION

For the reasons noted above, Appellant submits that the pending claims define patentable subject matter. Accordingly, Appellant requests that the Examiner's rejection of these claims be reversed and that the pending application be passed to issue.

Respectfully submitted,

Dated: December 22, 2005

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CLAIMS APPENDIX

1. An alignment verification device, comprising:

a spacer element having proximal and distal portions and an insert engaging element disposed on the distal portion; and

an alignment guide surface affixed to the spacer element and defining an alignment orifice, the alignment orifice being spaced apart from the insert engaging element.

2. The device of claim 1, wherein the insert engaging element is a generally rectangular element sized to fit within a slot formed on the surface of a spinal disc insert prosthesis.

3. The device of claim 2, wherein the insert engaging element further comprises a depth stop element.

4. The device of claim 1, wherein the spacer element includes two elongate members with the alignment guide fixed between the elongate members, each elongate member having an insert engaging element.

5. The device of claim 4, wherein each insert engaging element is a generally rectangular element sized to fit within a slot formed on the surface of a spinal disc insert prosthesis.

6. The device of claim 5, wherein at least one of the insert engaging elements includes a depth stop element.

7. A prosthesis alignment verification system, comprising:

an alignment verification device including

a spacer element having proximal and distal portions and a prosthesis engaging element disposed on the distal portion; and

an alignment guide surface affixed to the spacer element and defining an alignment orifice, the alignment orifice being spaced apart from the prosthesis engaging element; and

a prosthesis having an engaging element and a visual indicator element, the engaging element configured to releasably engage the prosthesis engaging element of the alignment verification device so that, upon engagement, the alignment orifice is spaced apart from the visual indicator element.

8. The system of claim 7, wherein the engagement of the alignment verification device with the prosthesis is adapted to permit a sighting element of an image obtaining device to be aligned with the alignment orifice and the visual indicator element so that an image obtaining device is aligned with the prosthesis in a known orientation.

9. The system of claim 8, wherein the prosthesis engaging element is generally rectangularly shaped and the engaging element of the prosthesis is a slot configured to engage the prosthesis engaging element.

10. The system of claim 9, wherein the prosthesis engaging element includes a depth stop element.

11. The system of claim 9, wherein the spacer element includes two elongate members, each having a prosthesis engaging element, and the prosthesis includes two engaging elements, each configured to engage one of the prosthesis engaging elements.

12. The system of claim 8, wherein the prosthesis is a spinal disc prosthesis.

13. The system of claim 12, wherein the spinal disc prosthesis incorporates an angle.

14. The system of claim 12, wherein the spinal disc prosthesis includes at least one bone facing surface having a slot as the engaging element, the prosthesis engaging element being sized to engage the slot.

15. The system of claim 14, wherein the spinal disc prosthesis includes two opposed bone facing surfaces each having a slot as the engaging element, the spacer element comprising two

elongate members each having a prosthesis engaging element sized to engage a slot on the spinal disc prosthesis.

16. The system of claim 7, further comprising a prosthesis inserter tool, the inserter tool having a prosthesis engaging element conforming substantially in shape to the prosthesis engaging element of the alignment verification device so that each prosthesis engaging element can engage the same engaging element on the prosthesis.

17. The system of claim 8, further comprising an orientable image obtaining device including a sighting element for aiding in orienting the image obtaining device, the sighting device being aimable through the alignment orifice to the visual indicator element to provide a visual indication that the image obtaining device is oriented in a predetermined orientation with respect to the prosthesis.

18. The system of claim 17, wherein the sighting element is a laser pointer.

19. A method for verifying the orientation of an image obtaining device with respect to an implanted prosthesis, comprising the steps of:

providing an alignment verification device including

a spacer element having proximal and distal portions and a prosthesis engaging element disposed on the distal portion; and

an alignment guide surface affixed to the spacer element and defining an alignment orifice, the alignment orifice being spaced apart from the prosthesis engaging element;

engaging the alignment verification device to the implanted prosthesis, the prosthesis having an engaging element and a visual indicator element, the engaging element configured to releasably engage the prosthesis engaging element of the alignment verification device so that, upon engagement, the alignment orifice is spaced apart from the visual indicator element;

orienting the image obtaining device so that a sighting element on the image obtaining device is aimed through the alignment orifice to the visual indicator element to provide a visual indication that a predetermined orientation between the image obtaining device and the prosthesis has been achieved.

20. The method of claim 19, further comprising the following steps before engagement of the alignment verification device to the implanted prosthesis:

providing an insertion tool having a prosthesis engaging element that conforms substantially in shape to the prosthesis engaging element of the alignment verification device so that the insertion tool engages the same engaging element on the prosthesis that the alignment verification device engages;

engaging the prosthesis to be inserted to the insertion tool;

implanting the prosthesis in a patient in a desired location; and

disengaging the insertion tool from the prosthesis.

21. The method of claim 20, wherein the alignment verification device is engaged to the prosthesis employing the same engaging element on the prosthesis from which the insertion tool was disengaged.

EVIDENCE APPENDIX

No evidence has been submitted.

RELATED PROCEEDINGS APPENDIX

There are no related proceedings.

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